

NHPF Issue Brief

No.790 / May 10, 2003



Medicaid Prescription Drug Coverage: State Efforts to Control Costs

Dawn M. Gencarelli, *Senior Research Associate*

OVERVIEW — *This paper provides a brief summary of the Medicaid prescription drug benefit. It explains the mechanisms being used by states to control their prescription drug spending within the Medicaid program. The paper also highlights some of the concerns that have been expressed with these mechanisms and the litigation that has been initiated in several states as a result of these efforts. It takes a closer look at three states with cost-containment strategies that have been the focus of increased scrutiny.*

Medicaid Prescription Drug Coverage: State Efforts to Control Costs

As state lawmakers try to meet the competing needs of their constituents in a time of ever-decreasing revenues, Medicaid prescription drug coverage has become a principal focus of states' cost-containment efforts. According to recent figures, states are facing deficits in the range of \$70 billion to \$85 billion for state fiscal year (FY) 2004.¹ In addition, more than two-thirds of the states report shortfalls in their 2003 budgets that together total at least \$17.5 billion.² Medicaid, which accounts for 15 percent to 20 percent of state spending (second only to education), has been a major contributor to these woes. Between 1997 and 2000, total Medicaid spending grew by 7.7 percent a year. And Medicaid drug expenditures grew more than twice as fast, rising by an average annual rate of 18.1 percent and accounting for nearly 20 percent of the increase in Medicaid spending for this period.³

To address Medicaid's impact on their budgetary crises, 44 states are considering freezing or reducing Medicaid eligibility, benefits, and reimbursement rates during the 2003 legislative session.⁴ Thirty-nine states anticipate changes in their Medicaid prescription drug programs.⁵ In 2002 alone, 210 bills on prescription drugs were considered in 39 states; 31 were passed.

States are implementing a wide range of policies to rein in prescription drug costs or are expanding those already in place. These actions have resulted in serious debate among the affected stakeholders: drug manufacturers, wholesalers, prescribers, pharmacies, and beneficiaries. Drug manufacturers and pharmacies have expressed concern about adequate reimbursement; prescribers worry about interference in their relationship with patients; and beneficiaries and their advocates worry about the affordability of and access to prescription drugs for low-income patients. These concerns are greatest in those states where multiple—in many cases, up to four or five—cost-cutting measures are being implemented simultaneously.

Increasing the tension and confusion around this issue has been the ongoing litigation that several states have faced as their efforts have been challenged in the courts. One such case has already reached the U.S. Supreme Court and is being closely monitored by other states that have their own draft legislation ready to be set in motion.

National Health Policy Forum

2131 K Street NW, Suite 500
Washington DC 20037

202/872-1390
202/862-9837 [fax]
nhpf@gwu.edu [e-mail]
www.nhpf.org [web]

Judith Miller Jones
Director

Judith D. Moore
Co-Director

Michele Black
Publications Director

NHPF is a nonpartisan education and information exchange for federal health policymakers.

MEDICAID PRESCRIPTION DRUG BENEFIT

Outpatient prescription drugs remain an optional benefit under federal Medicaid law. However, all states currently provide prescription drug coverage. As long as states opt to cover outpatient prescription drugs, they must cover all drugs approved by the Food and Drug Administration (FDA) that have been produced by those manufacturers that have entered into a rebate agreement with the secretary of the U.S. Department of Health and Human Services (DHHS).⁶ In cases where states have implemented a preferred drug list (PDL), federal Medicaid law allows certain drugs to be excluded, but these drugs must be made available through a prior authorization process (discussed in greater detail below). The price that the state pays for outpatient prescription drugs includes the amount the state pays the pharmacy for the drug itself and the fee the state pays the pharmacist for dispensing the drug.⁷ Under the Medicaid Drug Rebate Program, which was implemented as part of the Omnibus Budget Reconciliation Act of 1990, the state receives a rebate from the manufacturer for purchasing the drug.⁸ The act requires drug manufacturers to provide rebates to the states on a quarterly basis in exchange for states' reimbursement of their prescription drugs.⁹

Rebate amounts are established by federal statute and differ for brand-name and generic drugs. For brand-name drugs, the rebate is (a) the greater of 15.1 percent of the average manufacturer's price (AMP) or the difference between the AMP and the manufacturer's "best price"¹⁰ and (b) an additional rebate for any product whose price increased by more than the Consumer Price Index (CPI-U) since July 1, 1990.¹¹ AMP is the average price paid to manufacturers by wholesalers (after all discounts, including manufacturer rebates) for a particular dosage form and strength of a prescription drug distributed solely to the retail pharmacy class of trade.¹² The AMP is not a published price. For generic drugs, the rebate is equal to 11 percent of each product's AMP.¹³

Beyond coverage of all drugs whose manufacturers have entered into a federal rebate agreement, states are given significant flexibility in the design of their prescription drug benefit. Acceptable limitations on Medicaid drug coverage include the following:

- A covered drug may be subject to prior authorization as long as the system employed provides a response to a request within 24 hours and enables the dispensing of a 72-hour supply of the prescription drug in emergency situations.
- States are permitted to exclude a prescription drug from coverage if it falls into one of the following ten categories:
 - Drugs used for anorexia, weight loss, or weight gain.
 - Drugs used to promote fertility.
 - Drugs used for cosmetic purposes or hair growth.
 - Drugs used for the symptomatic relief of cough and colds.

States are given significant flexibility in the design of their prescription drug benefit.

- Drugs used for smoking cessation.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.
- Drugs that a manufacturer ties to the sale of additional tests or monitoring services purchased exclusively from the manufacturer or its designee.
- Barbiturates (powerful depressants that slow down the central nervous system).
- Benzodiazepines (medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders).¹⁴

This restricted drug list is subject to periodic updates from the DHHS secretary.

States may also establish formularies, provided they meet certain requirements. The formulary must be developed by a committee of physicians, pharmacists, and other individuals appointed by the governor. The formulary must include all drugs of any manufacturer that has entered into a rebate agreement with the secretary. An otherwise covered drug may be excluded from the formulary only if it does not have a “significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinically meaningful outcome” over other formulary drugs, with respect to the treatment of a given disease or condition. Drugs not contained in the formulary must be available through an established prior authorization process. States may also exclude drugs that are not being used for a “medically accepted indication.”¹⁵

States also have the authority to impose other restrictions, with respect to all drugs in a therapeutic class,¹⁶ including limitations on the quantity of drugs per prescription or the number of refills per prescription. These limitations must be necessary to “discourage waste, and may address instances of fraud or abuse.”¹⁷

Cost Sharing

Under federal Medicaid law, states are permitted to impose copayments on Medicaid beneficiaries for prescription drugs. Any copayment applied must be “nominal,” which has been defined as ranging from \$0.50 to \$3.00 per prescription, although waivers have been granted by the Centers for Medicare and Medicaid Services (CMS) that permit copayments as high as \$5.00 per prescription. Certain individuals, such as those under 18 years of age and pregnant women, as well as certain categories of services, such as emergency services and family planning, are exempt from copayments.¹⁸ Pharmacies providing drugs to Medicaid beneficiaries are prohibited from denying prescription drugs to anyone who is unable to furnish a copayment.¹⁹

States may also establish formularies, provided they meet certain requirements.

STATE MECHANISMS FOR CONTROLLING MEDICAID PRESCRIPTION DRUG SPENDING

The increasing budgetary pressure on states has led nearly all of them to closely examine their Medicaid programs and develop ways to bring costs under greater control. Of particular concern for states have been growing expenditures for prescription drugs. Drug product costs account for over 90 percent of Medicaid prescription drug expenditures, while pharmacist dispensing fees are less than 10 percent. The strategies employed by states to control their prescription drug spending vary greatly from state to state, but those that are most widely used can be captured within some general categories. The increased financial responsibility or administrative burden of each of these controls is distinct and may fall on beneficiaries, providers, pharmacies, or drug manufacturers. While each of these approaches may affect multiple stakeholders, they can be grouped into two general categories: (a) strategies that place some limits on beneficiary access to prescription drugs or increase the costs they incur and (b) strategies that reduce payments to pharmacies and require additional rebates from drug manufacturers.

Strategies Directed at Beneficiary Drug Utilization

Prior Authorization — Prior authorization requires prescribers to obtain approval before a prescription can be dispensed by a pharmacist to a Medicaid patient. Some states permit both prescribers and pharmacies to obtain prior authorization. This mechanism has been a part of state Medicaid programs for many years and has been used to control the use of costly drugs or those subject to abuse. Some argue that prior authorization, which is generally linked to a state's PDL, can serve as an important mechanism for states to control the use of unnecessary or extremely costly drugs. Between 35 and 40 states have some type of prior authorization program,²⁰ and it has been estimated that 27 of those states may alter their prior authorization rules during the 2003 legislative session.²¹ As noted above, state prior authorization programs must comply with the standards set forth in federal Medicaid law, which include a 24-hour response time and the provision of a 72-hour supply of a drug in emergency situations.²²

Concern about access to needed drugs has led many states to develop safeguards within their prior authorization programs. These safeguards include "grandfather" provisions for beneficiaries taking a nonpreferred drug, prior authorization based on age criteria, and maintenance of coverage for certain classes of drugs without prior authorization. Examples of these classes include certain mental health drugs, including antipsychotics and antidepressants, and certain drugs used for the treatment of HIV/AIDS.

Preferred Drug Lists/Formularies — Throughout the past few years, PDLs, or formularies, have become an effective tool for states looking to

control their prescription drug expenditures. A PDL is a list of drugs approved by a state that can be dispensed without prior authorization. As noted earlier, in order to comply with federal Medicaid law, such lists must be established by a committee that is appointed by the state's governor and must include physicians and pharmacists; the list must include all drugs of those manufacturers that have a rebate agreement with the federal government, unless a drug does not have a "significant, clinically meaningful therapeutic advantage over other formulary drugs"²³; and drugs excluded from a state's list must be available through a prior authorization process that meets certain requirements. In developing a PDL, the appointed committee reviews drugs by class (drugs with similar clinical indications and/or chemical composition). Based on each drug's effectiveness, safety, clinical outcome data, and cost, several from each class are selected for inclusion in the state's PDL. The state then negotiates for the lowest possible price for each drug on the list.

According to a survey conducted by the National Conference of State Legislatures, 32 states are contemplating the creation of PDLs or alteration of their existing PDLs during the 2003 legislative session.²⁴ Given the importance to manufacturers of having their drugs accessible without prior approval, states have found that their PDLs can serve as leverage in securing supplemental rebates from manufacturers.

Increased Use of Generic Drugs — Whether through mandatory substitution laws or through provider and pharmacy education and incentives, many states are working to steer patients away from costly brand-name drugs to less expensive generic alternatives. Given the potential savings that generics can offer and the relatively modest impact on most beneficiaries and providers, promoting their use has served as an important and effective cost-saving measure. According to a 1998 Congressional Budget Office report, generic drugs are approximately one-half the price of brand-name drugs during their first year on the market.²⁵ The actual cost to a state Medicaid program, however, may vary depending on the structure of its rebate program.

At least 15 states have opted to implement mandatory substitution that requires pharmacists to dispense a generic drug for a brand-name drug, when available.²⁶ Almost all of these programs include processes that allow physicians to prescribe a brand-name drug for a patient. In some states, physicians need only indicate their preference for the brand-name drug on the prescription itself, while others require physicians to obtain prior approval.

Some states have not gone as far as to require generic substitution but have opted instead to use financial incentives and education. For example, North Carolina recently promulgated a regulation that lowered the dispensing fee paid to pharmacies for brand-name drugs from \$5.60 to \$4.00 but maintained the higher fee for generic drugs as an incentive for pharmacies to dispense generics.²⁷ Other states have implemented

A PDL is a list of drugs approved by a state that can be dispensed without prior authorization.

or are considering limits on the number of brand-name drugs that any Medicaid patient may receive per month.²⁸ Many states also have differing consumer copayments for brand-name and generic drugs. These copayments, however, are so nominal that some argue that the differences may not lead to changes in consumer behavior. The federal prohibition against pharmacies' denying a Medicaid beneficiary a prescription drug if he or she is unable to furnish a copayment also constrains the usefulness of this approach.

Federal Medicaid law sets a limit, the federal upper limit, on the payment amount the federal government will match for drugs with three or more generic equivalents. The payment limit for these drugs is 150 percent of the published price for the *least* costly therapeutic equivalent that can be purchased by pharmacists (in quantities of 100 pills).²⁹ States may set their own payment ceilings for multiple source drugs—known as maximum allowable cost (MAC) limits—provided they are lower than the federal limits. In 2000, approximately 23 states set their own MAC limits, according to the National Pharmaceutical Council. These limits create an even greater incentive for pharmacists to dispense generics to Medicaid beneficiaries, when available.

Increased Copayments/Limits on Prescription Drugs — In 2000, 28 of 44 state Medicaid programs imposed copayments on prescription drugs.³⁰ These copayments ranged from \$0.50 to \$3.00 per prescription, the permissible limits within federal Medicaid law. Within these permissible limits, copayments were often higher for brand-name drugs. States with CMS-approved waivers have copayments as high as \$5.00 per prescription. As states continue to explore their options for reining in prescription drug costs, many are turning to increased beneficiary cost sharing. According to the Kaiser Commission on Medicaid and the Uninsured, 19 states plan to establish or increase beneficiary copayments for prescription drugs in FY 2003.³¹

One state's effort in this area has been challenged by pharmacies in court. In late 2002, the Oregon legislature instituted prescription drug copayments for Medicaid beneficiaries not enrolled in managed care. Effective January 1, 2003, patients were required to pay \$2.00 for generic drugs and \$3.00 for brand-name drugs. (Previously, Oregon had no copayment.) This has generated concern among pharmacies, which will ultimately absorb the cost of these increased copayments if Medicaid patients are unable to pay. Several pharmacies filed suit against the state in January, alleging a violation of federal Medicaid law. According to the Bureau of National Affairs, the complaint claims that the state implemented the new rule without evaluating the impact of the reduced reimbursement rate on pharmacies and Medicaid patients, as required by law.

In addition to increased copayments, states have used prescription drug limits for beneficiaries as a means of controlling costs. A number of states have had such limits in place for years. Others are now exploring them.

Many states are turning to increased beneficiary cost sharing.

At least 12 states are considering or have implemented policy changes that will initiate or expand prescription drug limits. These include limits on the number of prescriptions that Medicaid beneficiaries are entitled to fill each month or each year, limits on the designated number of days that constitutes a supply for each prescription, and caps on the number of refills permitted.³² In some cases, generics and certain classes of drugs are excluded from these limits. Several states have also instituted drug management programs for beneficiaries who receive more than a certain number of prescriptions per month.

While relatively stringent drug limits have been a common practice in many private-sector plans for years, consumer advocates are concerned that limits on prescription drugs for the Medicaid population may lead some beneficiaries to forgo necessary treatment because of cost. Others worry that limiting access to needed prescription drugs may ultimately lead to more costly treatments in the future.

Disease Management — More than 20 states are in the process of developing and implementing disease management programs for their Medicaid beneficiaries.³³ With almost 80 percent of total Medicaid expenditures attributable to the treatment of chronic conditions, including diabetes, asthma, and cardiovascular disease, states are looking to disease management programs as a means of targeting and monitoring high-risk individuals.³⁴ State disease management programs can be structured in a variety of ways. Some states outsource their programs to disease management organizations; others develop their own internal systems; others work with pharmaceutical companies; and some, like Florida, combine more than one approach. Some observers have expressed concern that disease management programs governed by pharmaceutical companies may place too great an emphasis on the use of pharmaceuticals rather than using a more comprehensive approach.

Missouri contracted with a health care technology company to develop its disease management program. The program involves both pharmacists and physicians and focuses on asthma, depression, diabetes, and heart failure. High-risk beneficiaries select a health care provider team that includes a physician and a pharmacist. Through patient and provider education, as well as an innovative software system, the program seeks to improve patient care and health outcomes and ensure the appropriate and efficient use of prescription drugs.

Pharmacy Benefit Managers and Health Maintenance Organizations — Some states, including Tennessee, have chosen to use pharmacy benefit managers (PBMs) to manage their prescription drug benefits. PBMs serve as intermediaries between the state Medicaid program and pharmaceutical manufacturers and are able to negotiate significant discounts. They often perform a variety of other services, including disease management.

Other states have pulled prescription drugs from their fee-for-service programs and rely on managed care organizations (MCOs) to manage their

More than 80 percent of total Medicaid expenditures are attributable to the treatment of chronic conditions.

prescription drug benefit. Unlike states, MCOs are not able to collect manufacturer rebates through the Medicaid Drug Rebate Program. Medicaid MCOs negotiate independently with drug manufacturers, either directly or through PBMs, in order to receive discounts and rebates.

Step Therapy/Fail First Policies — “Fail first” or “step therapy” policies are similar in their operation to prior authorization requirements. Before a physician is permitted to prescribe a newer, more expensive drug for a patient, the physician must demonstrate that the alternative (and less expensive) therapy has failed to prove effective for that patient. As they do with prior authorization requirements, states may apply fail first policies to individual drugs or to classes of drugs.³⁵ According to a survey conducted by the Kaiser Commission on Medicaid and the Uninsured, at least 11 states and the District of Columbia have fail first requirements for one or more drugs.³⁶

Strategies Directed at Drug Manufacturers and Pharmacies

Supplemental Rebates — In addition to the rebate required under federal Medicaid law, several states, including Maine and Florida, in yet another effort to reduce their total spending on Medicaid prescription drugs, have sought supplemental rebates from drug manufacturers. The way in which these state rebate programs are designed differs from state to state, but a key component generally involves the inclusion of the manufacturer’s drugs in a state’s PDL in exchange for the manufacturer’s provision of a supplemental rebate to the state. What may differ among the state programs is the process by which beneficiaries may access those drugs that are not included in the state’s PDL and the population that benefits from the discounted drugs. For example, in the design of its program, Maine Rx, the state of Maine has sought to extend discounted prescription drugs and rebates beyond the Medicaid population to all uninsured Maine residents—regardless of income.³⁷ In contrast, the Florida program secures supplemental rebates only for prescription drugs provided to those individuals within the Medicaid population.³⁸ As discussed later in the paper, both the Maine and Florida programs are the subject of pending litigation.

CMS issued an advisory on this issue in a letter to state Medicaid directors dated September 18, 2002. The intent of the letter was to clarify issues related to supplemental drug rebate agreements and prior authorization of Medicaid prescription drugs. The agency appeared to signal that such agreements are acceptable and that states may use prior authorization to encourage drug manufacturers to enter into these agreements.³⁹ Noting, however, that “the operation of a prior authorization program used to negotiate drug discounts for the Medicaid population is a significant component of a State plan,” the agency indicates that both the agreement and the prior authorization program require CMS approval.⁴⁰ States that procure benefits, rebates, or discounts for

non-Medicaid populations by linking them to a Medicaid prior authorization program must also submit their program for CMS review but are required to meet a more stringent standard. In such cases, "the state should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and objectives of the Medicaid program."⁴¹

Changes in Dispensing Fees and Reimbursement Formulas — Medicaid payments for prescription drugs include two components: (a) acquisition costs and (b) dispensing fees. Both the acquisition costs, which cover the cost of the drug itself, and the dispensing fees, which cover the cost of filling the prescription, are paid to the pharmacy.⁴² State payments are offset by rebates paid by drug manufacturers to the states in exchange for the state's coverage of all of the manufacturer's drugs.

For acquisition costs, federal Medicaid regulations place limits on what the federal government will match. For brand-name drugs or for generic drugs with fewer than three generic versions, the reimbursement to the pharmacist is the lower of (a) the pharmacist's usual and customary charge to the public and (b) the drug's estimated acquisition cost (EAC).⁴³ Most states use a drug's average wholesale price (AWP)⁴⁴ to calculate its EAC. Most states pay for drugs at a percentage discount below a drug's AWP, which ranged from AWP minus 4 percent in Wyoming to AWP minus 15.1 percent (for pharmacies with more than five stores) in Michigan in 2001.⁴⁵ Other states use a markup from a drug's wholesale acquisition cost,⁴⁶ and still others select the lower of the two calculations. In their continued efforts to control costs, many states are attempting to cut their payments to pharmacies by increasing the percentage discount below AWP at which they pay for drugs. Others are simply reducing dispensing fees. These initiatives are being met with significant resistance from drug stores and pharmacists.

Purchasing Pools — Many states are looking to form purchasing pools in order to increase their bargaining power with drug manufacturers and secure the lowest possible prices for prescription drugs. Within states, efforts are underway to pool purchases among state agencies that provide coverage for different populations, including Medicaid beneficiaries and state employees. In September 2001, a law went into effect in Texas that established a multi-agency bulk-purchasing program for prescription drugs. It combines prescription drug purchasing for, among others, the departments of health and mental health, state employees, teachers, and the state prison system. The state expects savings of \$13 million within the first two years.⁴⁷

States are also looking beyond their borders to increase their leverage with drug manufacturers. One initiative, the Northern New England Tri-State Prescription Drug Purchasing Coalition, involves the states of Vermont, Maine, and New Hampshire. In its first year, the coalition focused on pooling the Medicaid populations of the three states, totaling 330,000

Many states are attempting to cut their payments to pharmacies.

individuals, and was to expand to other groups in subsequent years. By increasing their purchasing power and efficiency, the three states are expected to save 10 percent to 15 percent per year.⁴⁸ The states have selected a pharmacy benefit manager to manage the pool.

Another nine states have banded together to form the National Legislative Association on Prescription Drug Prices, a nonprofit organization that would create PDLs and manage prescription drug benefits for state employees and Medicaid beneficiaries. As a nonprofit, the organization would negotiate discounts with manufacturers and pass the savings on to the consumers in the participating states.

Many other collective purchasing arrangements are being explored by states. Most of these efforts, including the above, are in the early stages of formation or discussion; consequently, their potential for savings cannot yet be evaluated.

Pharmacy Assessment Surcharges — Some states have elected to collect a fee for all retail pharmaceutical sales, raising concern among retail pharmacies that are also facing reduced dispensing fees and unpaid consumer copayments. Efforts by pharmacies in Massachusetts to pass these fees on to consumers have been met with a strict warning from state officials.

In regulations that went into effect on January 1, 2003, pharmacies in Massachusetts are required to pay a surcharge of \$1.30 for each non-Medicaid, non-Medicare prescription dispensed. This assessment is expected to generate \$36 million to offset increases in Medicaid drug costs. In response to the new regulations, pharmacies within the state began to impose the \$1.30 surcharge on consumers, informing them that they were required to do so. The regulations do not specify how pharmacies should pay the surcharge. The state attorney general subsequently issued a letter to the five major retail chains urging them to stop misleading the public and warned them that some pharmacies were violating the state's consumer protection laws.⁴⁹ In mid-February, the pharmacy chains agreed to absorb the cost of the assessment and one chain even agreed to reimburse individuals who had paid the \$1.30 since the regulation was put into place.⁵⁰ The charge is expected to drop to 65 cents in FY 2004, beginning on July 1.

Disclosure of Drug Company Marketing Activities — In an attempt to limit the influence that drug manufacturers have over the prescribing patterns of its state's physicians, Vermont passed legislation in June 2002 that requires pharmaceutical manufacturers to disclose to the state the "value, nature and purpose" of their marketing activities within the state. Free drug samples, clinical trials, and gifts with less than a \$25.00 value are exempt from the reporting requirements.⁵¹ The effects of this legislation may not be known for some time, since the first reports from drug manufacturers are not due until January 1, 2004. Similar legislation has been introduced in several other states, including Hawaii, Maryland, and Connecticut. These initiatives are not limited to Medicaid providers.

STATE EXAMPLES

Maine

The state of Maine has been carefully watched over the past several years because of a particularly controversial program that it has implemented in its effort to control prescription drug spending under its Medicaid program. Maine Rx, as it is known, would extend Medicaid discounts and rebates to all uninsured residents of Maine. Though the discounts provided through Maine Rx benefit individuals ineligible for Medicaid, the program directly affects Medicaid enrollees: a drug manufacturer's unwillingness to participate in the program triggers a prior authorization requirement for all the drugs it dispenses to Medicaid beneficiaries.⁵² This program has become mired in litigation and national political debate, with other states awaiting the outcome of this case to learn if the Maine law could become a reality within their own states. The Maine program has yet to be implemented and remains on hold following a challenge by the Pharmaceutical Research and Manufacturers Association (PhRMA). PhRMA believes the Maine law violates federal Medicaid law and amounts to an unconstitutional regulation of interstate commerce. PhRMA also argues that the prior authorization component of the program will cause harm to Medicaid beneficiaries by overly restricting access to needed medications. PhRMA objects to the state's extending "Medicaid-level discounts to non-Medicaid populations."⁵³

The Maine litigation reached the U.S. Supreme Court, where oral argument was heard on January 22. The Bush administration, business groups, and conservative legal organizations have lined up in support of PhRMA, while 28 states are backing Maine and approximately 12 are poised to quickly pass similar laws if the Court sides with the state. As noted by Maine's former commissioner of the Department of Human Services, Kevin Concannon, "as Maine goes, so goes the nation."⁵⁴ Whatever the Supreme Court decision, it is expected to lead to an appeal to Congress to act. The drug industry will be looking to prevent similar laws from passing in other states, and consumers and states will be looking for relief from rising drug costs. Several of the Supreme Court justices appear to be looking for guidance from the DHHS secretary.⁵⁵ The Court is expected to decide the case by this summer.

Michigan

Confronted with a 100 percent increase in Medicaid prescription drug costs between FYs 1999 and 2002, Michigan in February 2002 implemented the "Michigan Pharmaceutical Best Practices Initiative."⁵⁶ The program applies to 1.5 million Michigan residents in Medicaid and other public programs. The program established the Michigan Pharmaceutical Product List (MPPL), a list of preferred drugs that could be prescribed without prior authorization. The list includes: (a) those drugs deemed the

Michigan was confronted with a 100% increase in Medicaid prescription drug costs between FYs 1999 and 2002.

best drugs in their class, or “reference drugs,” by the state’s pharmacy and therapeutics committee; (b) those drugs for which the manufacturer has agreed to offer a supplemental rebate; and (c) drugs priced lower than the “reference drugs.” Drugs not included in the state’s PDL require prior authorization before dispensing. Limited exceptions were made for certain beneficiaries already taking antipsychotic medications, as well as for younger and older beneficiaries taking particular drugs.⁵⁷ The state expects to save \$850,000 per week under this program.⁵⁸

Mental health patients, their advocates, and other consumer advocate organizations have expressed serious concerns with the Michigan policy. These center on the delicate medication regimen for mental health patients and the potential harm to the health and safety of all consumers.⁵⁹ The Kaiser Commission on Medicaid and the Uninsured conducted a case study that found that the MPPL was more restrictive with regard to certain categories of drugs, including mental health, cardiac, and diabetes treatments, leading to decreased beneficiary access for these drugs. The report also raised questions about the process by which the MPPL was established and the way in which the program’s requirements were communicated to physicians, beneficiaries, pharmacies, and others.⁶⁰ Michigan’s program faced a legal challenge from mental health advocates and PhRMA, who raised questions about the process by which Michigan’s policy was approved, namely, that it was never considered by the full state legislature. The program was upheld by the Michigan Court of Appeals in December 2002. In March 2003, a U.S. District Court ruled that Michigan’s PDL, prior authorization, and supplemental rebate policies were acceptable under federal law. PhRMA and two patient groups have vowed to appeal this decision.

Florida

Spending for Medicaid prescription drugs increased by an average of 17 percent for each of the five years prior to 2001, eventually totaling \$1.3 billion in FY 2000, or 17 percent of Florida’s total Medicaid spending.⁶¹ Following an evaluation of its prescription drug spending, the state concluded that the increases it was experiencing were due primarily to doctors’ switching patients to high-priced drugs and to price increases in existing drugs. In response, in May 2001, legislation was passed, and a Medicaid state plan amendment was approved by DHHS Secretary Tommy Thompson, that allowed the state to negotiate directly with drug manufacturers for supplemental rebates of 10 percent for prescription drugs for Medicaid beneficiaries. Those drug manufacturers that provide such rebates will have their drugs included in the state’s list of preferred drugs. If a drug is not on the state’s list, doctors must get verbal authorization by calling a phone bank of pharmacists and pharmacy technicians before the prescription can be filled.

Florida’s spending for Medicaid prescription drugs increased by an average of 17% for each of the five years before 2001.

Drug manufacturers that prefer not to provide supplemental rebates have the option of offering programs, such as disease management, that can guarantee specified cost savings to the state. If a manufacturer's program fails to realize the stated savings, it will be required to make a payment to the state to account for the difference. Two drug manufacturers, Pfizer and Bristol-Myers Squibb, agreed to create programs for Florida Medicaid beneficiaries rather than provide supplemental rebates to the state. Pfizer's program involves disease management and health education that targets four chronic conditions, with a guaranteed savings to the state of \$33 million. Bristol-Myers Squibb's program focuses on improving the health of chronically ill Hispanics and African-Americans and reducing language and cultural barriers to care for Hispanic beneficiaries.⁶²

PhRMA filed suit in federal court in August 2001 in an effort to stop Florida's program. It argued that the program violated federal Medicaid law that requires states to cover all drugs of manufacturers that have entered into rebate agreements with the federal government.⁶³ The court sided with Florida and allowed the program to move forward. This decision was upheld at the appellate level in September 2002, granting the state yet another victory.

As with other programs that have the potential to limit access to certain drugs, the Florida program has been carefully monitored by consumer groups, who have identified safeguards that should be put in place to ensure proper functioning of the program. These include timely determinations of prior authorization and emergency provision of a short-term supply of a drug when timely determinations are not possible, beneficiary education, and staff qualified to make prior authorization decisions. Florida doctors have also expressed concern that the state's prior authorization program could have a negative effect on patient care by interfering with doctors' ability to choose the best drugs for their patients.⁶⁴

CONCLUSION

Faced with extraordinary pressure to find ways to reduce their Medicaid expenditures, states continue to look in many directions for solutions. A popular target of many of the states' efforts has been prescription drug spending. Efforts to control spending in this arena have been met with significant debate and controversy, both of which are likely to continue. Many issues will be debated and decided within the court system and future state efforts are likely to be determined by these judicial decisions. States will need to continue to find creative ways to control spending while ensuring access to needed prescription drugs for their low-income residents. The impact of state controls on each of the various stakeholders—beneficiaries, providers, drug manufacturers, and pharmacies—will need to be carefully assessed. From administrative requirements for prescribing physicians to lower reimbursement

for pharmacies and increased cost sharing for beneficiaries, each cost-saving measure will ask a particular stakeholder group to bear an increased burden. The extent of that burden and potential unintended consequences, including increased utilization of other health care services such as hospitalization, will need to be monitored by states, particularly those states where multiple strategies are being implemented simultaneously.

ENDNOTES

1. Iris J. Lav and Nicholas Johnson, "State Budget Deficits for Fiscal Year 2004 are Huge and Growing," Center on Budget and Policy Priorities, revised January 23, 2003; accessed February 3, 2003, at <http://www.cbpp.org/12-23-02sfp.pdf>.
2. Lav, "State Budget Deficits."
3. Andy Schneider and Linda Elam, "Medicaid: Purchasing Prescription Drugs," Kaiser Commission on Medicaid and the Uninsured, Washington, D.C., January 2002, 1.
4. National Conference of State Legislatures (NCSL), "2003 State Health Care Priorities Survey Report," Washington, D.C., December 2002.
5. NCSL, "2003 State Health Care."
6. Social Security Act, Section 1927(a)(1).
7. Schneider and Elam, "Medicaid: Purchasing," 11.
8. Schneider and Elam, "Medicaid: Purchasing," 11.
9. Social Security Act, Section 1927(k)(8).
10. The manufacturer's "best price" is the lowest price at which the manufacturer will supply the drug to any wholesaler, retailer, provider, health maintenance organization, or nonprofit or governmental entity in the United States. "Best price" does not include prices at which the manufacturer sells the drug to the Department of Veterans Affairs (the Federal Supply Schedule, or FFS, price), the Indian Health Service, state pharmaceutical assistance programs, community health centers, and certain other purchasers. Schneider and Elam, "Medicaid: Purchasing," 21.
11. For a discussion of prescription drug pricing, see Dawn M. Gencarelli, "Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?" Issue Brief No. 775, National Health Policy Forum, Washington, D.C., June 7, 2002, 8.
12. Gencarelli, "Average Wholesale Price," 8-9.
13. Gencarelli, "Average Wholesale Price," 9.
14. Social Security Act, Section 1927(d)(2).
15. Social Security Act, Section 1927(d)(4).
16. A group of drugs that is similar in chemical structure, pharmacological effect, and/or clinical use.
17. Social Security Act, Section 1927(d)(6).
18. Social Security Act, Section 1916(a)(2).
19. Social Security Act, Section 1916(e).
20. Linda Elam, Brian Bruen, and Jane Tilly, "Medicaid and the Prescription Drug Benefit: Cost Containment Strategies and State Experiences," Kaiser Commission on Medicaid and the Uninsured, Washington, D.C., September 2002, 9.

21. NCSL, "2003 State Health."
22. Social Security Act, Section 1927(d)(5).
23. Social Security Act, Section 1927(d)(4).
24. NCSL, "2003 State Health."
25. Anna Cook, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," Congressional Budget Office, July 1998.
26. Elam, Bruen, and Tilly, "Medicaid and the Prescription Drug Benefit," 8-9.
27. National Conference of State Legislatures (NCSL), "Recent Medicaid Prescription Drug Laws and Strategies, 2001-2003," Washington, D.C., updated January 30, 2003.
28. NCSL, "Recent Medicaid."
29. Schneider and Elam, "Medicaid: Purchasing," 17.
30. Schneider and Elam, "Medicaid: Purchasing," 6.
31. Kaiser Commission on Medicaid and the Uninsured, "State Budgets under Stress: How are States Planning to Reduce the Growth in Medicaid Costs?" Kaiser Commission on Medicaid and the Uninsured, Baltimore, July 30, 2002, 4.
32. Elam, Bruen, and Tilly, "Medicaid and the Prescription Drug Benefit," 10.
33. Lydia Faulkner, "Disease Management: The New Tool for Cost Containment and Quality Care," Center for Best Practices Issue Brief, National Governors Association, Washington, D.C., February 2003, 1.
34. Faulkner, "Disease Management," 1.
35. Schneider and Elam, "Medicaid: Purchasing," 11.
36. Vernon K. Smith, "Medicaid Budgets under Stress: A Survey of State Medicaid Programs for State Fiscal Year 2001 and 2002," Kaiser Commission on Medicaid and the Uninsured, Washington, D.C., October 2001. (Forty-four states responded to the Kaiser survey.)
37. Brannon P. Denning, "The Maine Rx Prescription Drug Plan and the Dormant Commerce Clause Doctrine: The Case of the Missing Link[age]," *American Journal of Law and Medicine*, 29 (2003): 7-30.
38. John Kasprak, "Florida Preferred Drug Formulary Law," Office of Legislative Research, Connecticut General Assembly, January 14, 2002, 2002-R-0082.
39. Dennis G. Smith, "Supplemental Drug Rebate Agreements," SMDL #02-014, letter to state Medicaid directors, Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, Baltimore, September 18, 2002.
40. Smith, "Supplemental Drug Rebate."
41. Smith, "Supplemental Drug Rebate."
42. Gencarelli, "Average Wholesale Price."
43. Gencarelli, "Average Wholesale Price," 6-7.
44. The AWP, or average wholesale price, of prescription drugs was intended to represent the average price at which wholesalers sell drugs to physicians, pharmacies, and other customers. In practice, it has become a pricing benchmark for prescription drugs with little to no connection to actual market prices for drugs. For more information on this topic, see Gencarelli, "Average Wholesale Price."
45. As reported by state drug program administrators in National Pharmaceutical Council Survey, "Pharmaceutical Benefits under State Medical Assistance Programs, 2001," Reston, Virginia.
46. A drug's "wholesale acquisition cost" (WAC) is the manufacturer's charge to the wholesaler to purchase the drug. The WAC is a published price and does not generally reflect any rebates or discounts. It is often referred to as the "catalogue" price.

47. National Governors Association (NGA), "Pharmaceutical Purchasing Pools," Center for Best Practices Issue Brief, Washington, D.C., October 24, 2001.
48. Office of Gov. Jeanne Shaheen, "Governors Shaheen, King and Dean Join Together To Create Tri-State Prescription Purchasing Pool," press release, Concord, New Hampshire, May 24, 2001.
49. Office of the Attorney General, "AG Reilly: Pharmacies Are Misleading Consumers about New \$1.30 Pharmacy Assessment Surcharge," press release, Commonwealth of Massachusetts, Boston, January 9, 2003.
50. 02133, "Issue: Prescription Drug Coverage for Seniors," Massachusetts Politics and Policy Online, Boston; accessed February 19, 2003, at <http://www.02133.org/issue.cfm?ID=54&CategoryID=7>.
51. NCSL, "Recent Medicaid."
52. Denning, "Maine Rx."
53. Robert S. Greenberger, "A Prescription for Change: Maine Drug Plan, Awaiting High Court Review, May Sway U.S.," *Wall Street Journal*, January 15, 2003, B2.
54. Greenberger, "Prescription for Change."
55. Lyle Denniston, "Supreme Court Wants U.S. to Weigh in on Maine Rx," Boston Globe Online, January 23, 2003, A3.
56. James K. Haveman Jr., "Michigan Pharmaceutical Best Practices Initiative," Michigan Department of Community Health, slide presentation at National Conference of State Legislatures annual meeting, Denver, July 26, 2002; accessed May 7, 2003, at http://www.kaisernetwork.org/health_cast/uploaded_files/MI-Rx-Viele-02Jul.pdf.
57. Cathy Bernasek, Jeff Farkas, Helene Felman, Catherine Harrington, Dan Mendelson, and Rajeev Ramchand, "Case Study: Michigan's Medicaid Prescription Drug Benefit," Kaiser Commission on Medicaid and the Uninsured, Washington, D.C., January 2003.
58. Haveman "Michigan Pharmaceutical."
59. Lisa Ruby, "Changes in Medicaid Prescription Coverage," Michigan Poverty Law Program Newsletter, Winter 2002; accessed January 28, 2003, at <http://www.mplp.org/materials/Newsletter/02Winter/Publicbenefits2.htm>.
60. Bernasek et al., "Case Study."
61. Office of Program Policy Analysis and Government Accountability, "Growth in Medicaid Prescription Drug Costs Indicates Additional Prudent Purchasing Practices Are Needed," *OPPAGA Justification Review*, Report No. 01-10, Florida Legislature, Tallahassee, Florida, February 2001.
62. National Governors Association, "Addendum to State Pharmaceutical Assistance Programs, Public-Private Partnerships," National Governors Association, Washington, D.C., October 2001.
63. Kasprak, "Florida Preferred."
64. Tanya Albert, "PhRMA Sues Florida over Medicaid Formulary," *AMNews*, September 3, 2001; accessed January 30, 2003, at http://www.ama-assn.org/sci-pubs/amnews/pick_01/gvsc0903.htm.